

The National Task Force on CME Provider/Industry Collaboration is committed to fostering, furthering and enhancing quality Continuing Medical Education (CME).

Volume 2, Issue 1

## Pharmaceutical, Biotechnology and Medical Device Company Support of Continuing Medical Education

*Pharmaceutical, biotechnology and medical device companies (industry) provide funding and in kind support for certified, independent continuing medical education (CME). Those same companies also fund industry-produced, Food and Drug Administration (FDA) regulated activities, sometimes referred to as promotional education. This FACT SHEET describes industry support of certified, independent CME. A subsequent FACT SHEET will discuss industry-produced FDA regulated activities.*

- The pharmaceutical, biotechnology and medical device industries play a significant role in informing healthcare professionals about the availability, value, and proper use of medications, vaccines, and medical devices. The Association of American Medical Colleges (AAMC) states in its 2008 [Report of the AAMC Task Force on Industry Funding of Medical Education](#) that "Substantive, appropriate, and well-managed interactions between industry and academic medicine are vital to public health..." The report goes on to add that those interactions "...must be conducted in a way that is principled and upholds the public trust".<sup>1</sup> These principles apply to all areas of interaction between industry and the health professions including grant support for certified CME.
- These industries have adopted voluntary guidelines on interactions with healthcare professionals. The PhRMA and AdvaMed Codes provide guidance on how industry employees and its agents should maintain legal and ethical relationships in their interactions with healthcare professionals.<sup>2,3</sup> Pharmaceutical, biotechnology and device companies must also comply with guidelines on industry support of CME as issued by the FDA. Additionally, those companies that support CME also must be in compliance with fraud and abuse and anti-kickback laws, and other criminal and civil regulations as set forth in the 2003 Office of the Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers.<sup>4</sup> Moreover, the PhRMA Code recommends that companies develop objective criteria for making CME grant decisions to ensure that the activity funded by the company is a bona fide educational activity and that the financial support is not an inducement to prescribe or recommend a particular medicine or course of treatment.<sup>2</sup> The company then provides funding in the form of an educational grant to an educational provider, for example a medical school, organization or agency that manages the grant funds and is responsible for ensuring independence from commercial influence. In all cases, the company has no input into the faculty selection or content of the educational activity.
- In accordance with adult education principles as well as the requirements of the CME credit systems and the ACCME, CME should address the documented educational needs of healthcare professionals and should support evidence-based quality improvement and performance improvement initiatives. Continuing medical education support comes from a variety of sources, with the substantial majority of CME providers utilizing industry funding to help fulfill their missions.<sup>5</sup> The CME activities that are supported by industry must be unbiased, open to a variety of viewpoints, and must not serve as marketing or promotional vehicles for industry.<sup>1</sup>
- Educational institutions, organizations or agencies that receive commercial support must comply with the guidelines and standards of their respective oversight bodies (eg, AAFP, ACCME, ACPE, AMA, ANCC, AOA, others).<sup>6</sup> These requirements help assure that industry-funded certified CME is independent of supporting companies' influence and control of CME content, faculty and outcomes. Many of these organizations review and monitor compliance regularly.<sup>7</sup>
- Progress to ensure the complete separation of promotional activities from the support of independent certified CME has been recognized and acknowledged. For example, the U.S. Senate Finance Committee Report issued in April of 2007 stated that the pharmaceutical industry has 'taken steps to separate grant making for educational programs [activities] from their marketing efforts' since the issuance of the 2003 HHS OIG Compliance Guidance.<sup>8</sup>

1. [https://services.aamc.org/Publications/index.cfm?fuseaction=Product.displayForm&prd\\_id=232&prv\\_id=281](https://services.aamc.org/Publications/index.cfm?fuseaction=Product.displayForm&prd_id=232&prv_id=281)

2. <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>

3. <http://www.advamed.org/NR/rdonlyres/D96644D9-7FA9-4DCC-B944-F00A8351FE57/0/AdvaMedCodeofEthicswithFAQ.pdf>

4. <http://www.oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>

5. [http://www.accme.org/dir\\_docs/doc\\_upload/207fa8e2-bdbe-47f8-9b65-52477f9faade\\_uploaddocument.pdf](http://www.accme.org/dir_docs/doc_upload/207fa8e2-bdbe-47f8-9b65-52477f9faade_uploaddocument.pdf)

6. American Academy of Family Physicians (AAFP), Accreditation Council for Continuing Medical Education (ACCME), Accreditation Council for Pharmacy Education (ACPE), the American Medical Association (AMA), American Nurses Credentialing Center (ANCC) and the American Osteopathic Association (AOA)

7. See the FDA Final Guidance <http://www.fda.gov/cder/guidance/isse.pdf>

8. <http://www.finance.senate.gov/press/Bpress/2007press/prb042507a.pdf>